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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Wortzman, Gordon, Gans, Patel

Serial No.: 09/864,083

Filed: May 23, 2001

Attorney Docket No.: 01-40076-US

COMPOSITIONS FOR THE TREATMENT
OF PIGMENTATION DISORDERS AND
METHODS FOR THEIR MANUFACTURE

REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This reply brief is filed in response to the Examiner's Answer mailed on May 23, 2005, and before the deadline of July 23, 2005. It is submitted in triplicate.

The Commissioner is hereby authorized to charge any fees which may be required during the entire pendency of the appeal, or credit any overpayment, to Deposit Account 18-0586.

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I. Real Party in Interest:

The real party in interest is as stated in Applicant's opening brief.

II. Related Appeals and Interferences:

Applicant's statement on the related appeals and interferences is incorporated by reference from Applicant's opening brief.

III. Status of Claims:

The status of the claims is as stated in Applicant's opening brief.

IV. Status of Amendments:

No amendments have been filed subsequent to the Final Rejection.

V. Summary of the Invention:

The Summary of the Invention is as stated in Applicant's opening brief.

VI. Issues:

The issues are as stated in the Applicant's opening brief.

VII. Grouping of Claims:

The grouping of claims is as stated in the Applicant's opening brief.

VIII. Argument:

The Examiner has not addressed numerous of Applicant's arguments raised in Applicant's opening brief as is required in MPEP 1208 ("The answer should contain a response to the allegations or arguments in the brief[.].")

ISSUE 1

Whether claims 1-23 are nonobvious in view of Gordon.

Applicant notes that the Examiner has not addressed numerous of Applicant's argument raised in the opening brief.

The Examiner has not responded to Applicant's argument that the Examiner has not met the prima facie case of obviousness. The Examiner fails to provide express support for the Examiner's assertion that Gordon provides some suggestion or motivation to substitute the "active agents" or modify the pH. (See April 23, 2003 Office Action, p. 3). The Examiner is required to provide express support from the art cited against Applicant, as opposed to merely stating that some suggestion or motivation exists or would be within the "skilled level of the artisan . . . absent evidence to the contrary." *Id.* See MPEP 2144.08. Nothing cited by the Examiner expressly supports her purported obvious modification of the Gordon reference. Additionally, the Examiner has not provided a declaration if the Examiner's own knowledge is the support relied upon. See 37 C.F.R. 1.104(d)(2). The Examiner neglects to even address this argument, which she was required to do. MPEP § 1208 ("The answer should contain a response to the allegations or arguments in the brief[.]") Since the Examiner did not address this argument, we are left to conclude that the Examiner concedes the point.

Even *assuming arguendo* that the Examiner met the burden of establishing a prima facie case of obviousness, the Examiner did not respond to Applicant's refutation of the obviousness rejection. The Examiner did not address the three examples of U.S. Patents cited by Applicant in support of the following: Conventional wisdom was to use a pH of 3.3 to 4.0 for stable compositions with 4% or less hydroquinone (the Food and Drug Administration permits only this amount), and Applicant's higher pH was not suggested in Gordon. See, e.g., Ex. 1, U.S. Patent No. 5,889,054, col. 7, lines 54-56 and col. 13, lines 19-21, U.S. Patent No. 5,962,526, col. 7, lines 49-51 and U.S. Patent No. 5,554,652, col. 7, lines 59-61. Since the Examiner did not

address this argument, we are left to conclude that the Examiner concedes the point, and these rejections should be removed for the claims in Groups 1-7.

ISSUE 2

Whether claims 1-9 are nonobvious over Lukenbach in view of Gordon.

The Examiner also failed to address several of Applicant's arguments in connection with this rejection. No response was offered to Applicant's argument that a prima facie case of obviousness had not been established because Gordon does not teach the specified pH range, while Lukenbach does not teach the combination of hydroquinone and cationic salts of acidic ascorbyl esters. In fact, Lukenbach teaches hydroquinone (without magnesium ascorbyl phosphate) compositions at about 7.5 pH (Lukenbach, Example 100C) and other compositions with magnesium ascorbyl phosphate (without hydroquinone) at about 7.5 pH (Lukenbach, Example 100B); each of these compositions were unstable and not aesthetically pleasing. Since the Examiner offers no response to these arguments, we must conclude that the Examiner concedes the point.

Additionally, the Examiner has not responded to Applicant's proof that there are unexpected results or advantages, which support the patentability of this invention. The stable, non-discoloration feature of the invention sufficiently establishes that an unexpected result is exhibited by the claimed composition, thereby meeting the statutory requirement of nonobviousness of 35 U.S.C. §103. See Supplemental Declaration by Philip J. Gordon (filed December 10, 2003)(attached to Applicant's opening brief as Exhibits 1-3). Neither Lukenbach nor Gordon addresses additional problems solved by the present invention, including the discoloring and/or oxidation which Applicant's composition overcomes. Applicant submits that the stability of Applicant's composition, i.e. the combination of the claimed compounds in the specified pH range, is a result unexpected by those skilled in the art. Specifically, Example

100B of Lukenbach, containing magnesium ascorbyl phosphate, began to brown and separate within days after mixing and additionally showed flocculation after a mere two weeks. (see Gordon Declaration, paragraph 4, attached to Applicant's opening brief). While Example 100C also discolored within days of mixing, and further exhibited signs of hydroquinone degradation within the first two weeks after mixing. (See Gordon Declaration, paragraphs 6 and 7, attached to Applicant's opening brief). Cosmetic formulations must be stable and aesthetically acceptable. One of ordinary skill in the art would not expect the combination of the active agents in these unstable formulations to result in a stable, cosmetically pleasing formulation. Thus, as compared to Lukenbach's embodiments, the stability and resulting pleasing aesthetics of the present invention are unexpected in the applicant's invention and is not rendered obvious by Lukenbach and Gordon. The Examiner did not mention this evidence at all, let alone respond to Applicant's arguments based on it as is required by MPEP § 1208. We must conclude that the Examiner has no argument in response, and that the claims are patentable.

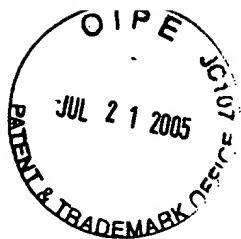
Consequently, Applicant traverses the 35 U.S.C. §103(a) rejections and respectfully requests their reconsideration and removal.



CONCLUSION

In view of the foregoing discussion and Applicant's opening brief, it is respectfully submitted that the Examiner's rejections of claims 1-23 (Groups 1 to 7) are improper and should be reversed by the Board.

<p>Express Mail Label No. <u>EV 482 561 513 US</u></p> <p>Date of Deposit <u>July 21, 2005</u></p> <p>I hereby certify that this paper, and the papers and/or fees referred to herein as transmitted, submitted or enclosed, is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" on the date indicated above and are addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p> <p>Name: <u>Maryellen Feehery</u></p> <p>Signature <u>Maryellen Feehery</u></p>	<p>Respectfully submitted,</p> <p>REED SMITH LLP</p> <p><u>Maryellen Feehery</u></p> <p>Maryellen Feehery Registration No.: 44,677 William J. McNichol, Jr. Registration No. 31,179 2500 One Liberty Place 1650 Market Street Philadelphia, PA 19103-7301 (215) 241-7988 Attorneys for Applicant</p>
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IX. APPENDIX

1. (original) A composition for the treatment of pigmentation disorders comprising:

hydroquinone; and

a cationic salt of acidic ascorbyl esters,

said composition having a pH of about 5.5 to about 8.0.
2. (original) The composition of claim 1 wherein the pH is about 5.5 to about 7.5.
3. (original) The composition of claim 1 wherein the pH is about 6.0 to about 7.5.
4. (original) The composition of claim 1 wherein the hydroquinone is present in about 1 to about 12 %.
5. (original) The composition of claim 1 wherein the hydroquinone is present in about 2 to about 10 %.
6. (original) The composition of claim 1 wherein the hydroquinone is present in about 2 to about 8 %.
7. (original) The composition of claim 1 wherein the hydroquinone is present in about 3 to about 4 %.
8. (original) The composition of claim 1 wherein the hydroquinone is present in about 4%.
9. (original) The composition of claim 1 further comprising a water-soluble antioxidant.
10. (original) The composition of claim 9 wherein the antioxidant comprises a sulfite.
11. (original) The composition of claim 9 wherein the antioxidant comprises sodium metabisulfite.
12. (original) The composition of claim 11 wherein the sodium metabisulfite is present in at least about 0.05%.

13. (original) The composition of claim 11 wherein the sodium metabisulfite is present at about 0.05% to about 0.5%.
14. (original) The composition of claim 1 wherein the cationic salt comprises an inorganic salt.
15. (original) The composition of claim 1 wherein the cationic salt comprises magnesium ascorbyl phosphate.
16. (original) The composition of claim 15 wherein the magnesium ascorbyl phosphate is present in at least about 0.1%.
17. (original) The composition of claim 15 wherein the magnesium ascorbyl phosphate is present at about 0.25 to about 3%.
18. (original) The composition of claim 15 wherein the magnesium ascorbyl phosphate is present at about 0.25 to about 1%.
19. (original) The composition of claim 9 wherein the antioxidant comprises sodium metabisulfite and the cationic salt comprises magnesium ascorbyl phosphate.
20. (original) The composition of claim 19 wherein the sodium metabisulfite is present in at least about 0.05% and the magnesium ascorbyl phosphate is present in at least about 0.5%.
21. (original) The composition of claim 1 wherein the cationic salt comprises an amino acyl derivative.
22. (original) The composition of claim 21 wherein the cationic salt comprises aminopropyl ascorbyl phosphate.
23. (original) The composition of claim 1 wherein the cationic salt comprises a sodium ascorbyl phosphate.

Claims 24-116 (withdrawn)